16.19.4.17 PHARMACIST CLINICIAN:

D. Prescriptive authority, guidelines or protocol:

(1) Only a registered pharmacist clinician with current protocols, registered with the New Mexico medical board or the New Mexico board of osteopathic medical examiners, may exercise prescriptive authority.

(2) A pharmacist clinician seeking to exercise prescriptive authority shall submit an application to the board. The application must include the supervising physicians' name and current medical license, protocol of collaborative practice and other information requested by the board. A pharmacist may submit the application with the initial application for certification or as a separate application after becoming certified and registered as a pharmacist clinician.

(3) The protocol will be established and approved by the supervising physician as set forth in these regulations and will be kept on file at each practice site of the pharmacist clinician and with the board.

(4) The protocol must include:

(a) name of the physician(s) authorized to prescribe dangerous drugs and name of the pharmacist clinician;

(b) statement of the types of prescriptive authority decisions the pharmacist clinician is authorized to make, including, but not limited to:

(i) types of diseases, dangerous drugs or dangerous drug categories involved and the type of prescriptive authority authorized in each case;

(ii) ordering laboratory and other tests appropriate for monitoring of drug therapy;

~~(ii)~~(iii) procedures, decision criteria or plan the pharmacist clinician is to follow when exercising prescriptive authority;

(c) activities to be followed by the pharmacist clinician while exercising prescriptive authority, including documentation of feedback to the authorizing physician concerning specific decisions made; documentation may be made on the prescriptive record, patient profile, patient medical chart or in a separate log book;

(d) description of appropriate mechanisms for consulting with the supervising physician, including a quality assurance program for review of medical services provided by the pharmacist clinician, (this quality assurance program will be available for board review); and

(e) description of the scope of practice of the pharmacist clinician.

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 15 DANGEROUS VETERINARY DRUGS - RETAIL DISTRIBUTION

16.19.15.1 ISSUING AGENCY: Regulation and Licensing Department, Board of Pharmacy, 1650 University Blvd, NE - Ste. 400B, Albuquerque, NM 87102, (505) 841-9102.
[02-15-1889...02-15-96; 16.19.15.1 NMAC - Rn, 16 NMAC 19.15.1, 03-30-02]

16.19.15.2 SCOPE: All retail veterinary drug distributors.
[02-15-96; 16.19.15.2 NMAC - Rn, 16 NMAC 19.15.2, 03-30-02]

16.19.15.3 STATUTORY AUTHORITY: Section 61-11-14.B. (13) NMSA 1978 authorizes the Board of Pharmacy to issue drug permits for wholesalers, retailers and distributors of dangerous drugs limited to veterinary use. Section 26-3-3(A) NMSA 1978 (the Drug Product Selection Act or "DPSA") authorizes pharmacists to dispense lower cost versions of multiple-source drugs that meet a final determination of the federal government that is published in the federal register. Section 26-3-2 of the DPSA states that the purpose of the DPSA is to assure that all New Mexico citizens continue to receive high quality drugs at a reasonable cost.
[02-15-96; A, 04-30-98; 16.19.15.3 NMAC - Rn, 16 NMAC 19.15.3, 03-30-02]

16.19.15.4 DURATION: Permanent.
[02-15-96; 16.19.15.4 NMAC - Rn, 16 NMAC 19.15.4, 03-30-02]

16.19.15.5 EFFECTIVE DATE: February 15, 1996, unless a different date is cited at the end of a Section or Paragraph. This Part reformatted for inclusion into the New Mexico Administrative Code (NMAC) effective 2-15-96.
[02-15-96; A, 04-30-98; 16.19.15.5 NMAC - Rn, 16 NMAC 19.15.5, 03-30-02]

16.19.15.6 OBJECTIVE: The objective of Part 15 of Chapter 19 is to establish standards to be followed by retailers and distributors for the safe and competent delivery, distribution, and disposal of dangerous drugs limited to veterinary use~~.~~ and to carry out the purpose of the Drug Product Selection Act by providing a uniform standard for drug product selection of animal drugs. Section 26-3-3(A) NMSA 1978 permits a pharmacist to select a lower cost multiple source drug that meets a final determination in the federal register when a more costly version of the drug is prescribed. Animal drugs approved by FDA are subject to final determinations in the federal register and therefore qualify for drug product selection as described in this regulation.

[02-15-96; 16.19.15.6 NMAC - Rn, 16 NMAC 19.15.6, 03-30-02]

16.19.15.7 DEFINITIONS:

A. "Limited licensure for retailers of veterinary drugs", means a license issued in accordance with the Pharmacy Act 61-11-14.B (13), which authorizes licensees to retail dangerous drugs limited to veterinary use, in accordance with the labeling provisions of the Drug and Cosmetic Act.

B. "Dangerous Drug" means a drug...because of any potentiality for harmful effect or the method of its' use, or the collateral measures necessary to its' use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such drug, and hence for which adequate directions for use cannot be prepared.

C. "Animal drug" means a dangerous (prescription) drug that is the subject of an approved New Animal Drug Application or an approved Abbreviated New Animal Drug Application under the Federal Food, Drug, and Cosmetic Act.

D. "FDA" means the United States Food and Drug Administration.

~~C~~E. "Adequate directions for use" means directions under which the layman can use a drug safely and for the purpose for which it is intended. A dangerous drug shall be sold at retail only on the order or prescription of a practitioner licensed by law to administer or prescribe such drug, if it bears the legend: "CAUTION -- Federal law restricts this drug to use by or on the owner of a licensed veterinarian".

~~D~~F. "Licensed Practitioner" means a person engaged in a profession licensed by the state, who within the limits of his license, may lawfully prescribe, dispense or administer drugs for the treatment of a patient's condition, and includes doctors of medicine, osteopathy, dentistry, podiatry and veterinary medicine.

~~E~~G. "Prescription" means an order given individually for the person for whom prescribed, either directly from the prescriber or indirectly by means of a written order, signed by the prescriber and shall bear the name and address of the prescriber, his license classification, the name and address of the patient, the name and quantity of the drug prescribed, directions for use and the date of issue. No person other than a licensed practitioner shall prescribe or write a prescription.

H. "Therapeutically equivalent" means animal drug products which have the same amount of the active drug in the same dosage form which when administered can be expected to provide the same therapeutic effect.

~~F~~I. "Expiration Date" means those drugs and particularly those that are biologic in origin, on which the label is required to bear an expiration date limiting the period during which the drug may be expected to have the labeled potency if it is stored as directed.

~~G~~J. "Proper Storage Temperature" means the temperature at which the label on the drug indicates the product must be kept.

(1) Cold -- any temperature not exceeding 46 degrees F.
(2) Cool -- any temperature between 46 and 50 degrees F.
(3) Room temperature -- the temperature prevailing in a working area.
(4) Controlled room temperature -- temperature maintained thermostatically between 59 and 86 degrees F.
(5) Excessive heat -- any temperature above 104 degrees F.
(6) Protection from freezing -- where, in addition to the risk of breakage of the original container, freezing subjects a product to a loss of strength or potency, or to destructive alteration of the dosage form. The container label bears the appropriate notice to protect from freezing.

[03-07-80...08-27-90, 04-30-98; 16.19.15.7 NMAC - Rn, 16 NMAC 19.15.7, 03-30-02]

16.19.15.8 MANUFACTURER'S LABEL: Retail distribution of veterinary drugs which by federal law require the manufacturer to label the following legend: "CAUTION: Federal law restricted this drug to use or on the order of a licensed veterinarian" shall be as follows:

A. shall be sold at retail by the licensee or an employee or employees designated by the licensee only on the written order or prescription of a veterinarian licensed in this state; or

B. if the order or prescription is other than a written order, the designated individual receiving the oral order or prescription shall immediately reduce such order to writing and the person receiving the order shall indicate the following information on the written record.

(1) name and address of the licensed veterinarian;
(2) name and strength of drug prescribed;
(3) quantity of drug ordered by the veterinarian;
(4) directions for use and cautionary statements, if given, by the veterinarian prescriber;
(5) date of order;
(6) name of owner and/or consignee of animal or animals;
(7) name of individual taking order from veterinarian prescriber.

[03-07-80...08-27-90; 16.19.15.8 NMAC - Rn, 16 NMAC 19.15.8, 03-30-02]

16.19.15.9 DANGEROUS VETERINARY DRUGS: All dangerous drugs distributed at retail on the order of a licensed veterinarian by the limited retail veterinary drug distributor shall be sold in the original, unbroken manufacturer's containers.

[03-07-80...08-27-90; 16.19.15.9 NMAC - Rn, 16 NMAC 19.15.9, 03-30-02]

16.19.15.10 ANIMAL DRUG PRODUCT SELECTION

A. Upon receipt of a prescription for an animal drug, a pharmacist may dispense any lower cost animal drug that is:

(1) therapeutically equivalent to the prescribed animal drug;
(2) bioequivalent to the prescribed animal drug; and
(3) listed in FDA's list of approved animal drug products (the "Green Book").

B. When performing animal drug product selection pursuant to this regulation, a pharmacist may rely on the bioequivalence information found in the FDA FOIA Summaries published on the FDA internet website.

C. A licensed practitioner may prohibit animal drug product selection by writing with his hand the words "no substitution" or the diminution "no sub" on the face of a prescription.

D. If animal drug product selection occurs as permitted in this regulation, the pharmacist shall indicate on the label of the dispensed container the brand of drug prescribed and the name of the drug dispensed.

E. A pharmacist may not select a therapeutically equivalent animal drug unless he passes on to the purchaser all savings between the net cost of the product prescribed and the product dispensed.

16.19.15.~~10~~11 DRUGS, LABEL CONTENT:

A. All such drugs shall be labeled by the licensed retail distributor as follows:

(1) name and address of the retail distributor;
(2) consecutively numbered prescription or order number;
(3) date of the prescription, or in the case of a refill, the date of the refill of the original order or prescription;
(4) name and address of licensed veterinarian prescriber;
(5) name of owner and/or consignee of the animal or animals;
(6) directions for use and cautionary statements, if any, contained in the order or prescription.

B. The attached label, where possible, will not obstruct the manufacturer's label.

[03-07-80...08-27-90; 16.19.15.10 NMAC - Rn, 16 NMAC 19.15.10, 03-30-02]

16.19.15.~~11~~12 PACKAGE INSERT: The package insert shall be left in the dispensed container, unless the prescribing veterinarian indicates on the prescription that it be removed by the dispenser.

[03-07-80...08-27-90; 16.19.15.11 NMAC - Rn, 16 NMAC 19.15.11, 03-30-02]

16.19.15.~~12~~13 LABELS, CASE LOT DISTRIBUTION:

A. Labels as required in Section 10 of this Regulation shall be placed on each drug container when quantity is in less than case lot distribution.

B. If the prescriber orders in quantities of case lot or carton, which is the same strength and dose units, the label shall be placed on each case or carton.

[03-07-80...08-27-90; 16.19.15.12 NMAC - Rn, 16 NMAC 19.15.12, 03-30-02]

16.19.15.~~13~~14 DANGEROUS VETERINARY USE DRUGS, MISBRANDED: Dangerous veterinary use drugs which are distributed at retail without the label required in Section 10 of this regulation shall be deemed to be misbranded under the provisions of the New Mexico Drug and Cosmetic Act and the federal law.

[03-07-80...08-27-90; 16.19.15.13 NMAC - Rn, 16 NMAC 19.15.13, 03-30-02]

16.19.15.~~14~~15 AUTHORIZATION:

A. A prescription or order of a licensed veterinarian shall not be refilled without the authorization of the prescribing veterinarian. If such authorization is other than written authorization, indicate the information on the back of the original order or prescription with the date of such authorization and the signature of the individual receiving such authorization from the prescriber.

B. A prescription or order shall be valid for no more than 12 months from the date of issue.

[03-07-80...08-27-90; 16.19.15.14 NMAC - Rn, 16 NMAC 19.15.14, 03-30-02]

16.19.15.~~15~~16 NUMBERED PRESCRIPTIONS: Prescriptions or orders must be consecutively numbered and filed by the retail veterinary drug distributor. Such files shall be kept for three years.

[03-07-80...08-27-90; 16.19.15.15 NMAC - Rn, 16 NMAC 19.15.15, 03-30-02]

16.19.15.~~16~~17 INVOICES AND RECORDS FOR DANGEROUS VETERINARY DRUGS: All procurement invoices and distribution records for dangerous veterinary drugs shall be kept for three years and shall be open to the inspection by an enforcement officer of the State.

[03-07-80...08-27-90; 16.19.15.16 NMAC - Rn, 16 NMAC 19.15.16, 03-30-02]

16.19.15.~~17~~18 STOCK OR INVENTORY OF DANGEROUS VETERINARY DRUGS:

A. All stock or inventory of dangerous veterinary drugs shall be maintained in an area not accessible to the public. Such area shall provide for the proper storage of drugs with adequate ventilation, lighting, temperature controls and refrigeration as may be required.

B. Purchase, storage and control of dangerous drugs shall be such as to prevent having outdated or deteriorated drugs in stock. Expiration dated drugs shall be checked periodically for outdated products. Outdated products shall be returned to the supplier or destroyed.
[03-07-80...08-27-90; 16.19.15.17 NMAC - Rn, 16 NMAC 19.15.17, 03-30-02]

16.19.15.~~18~~19 DISPOSAL OF INVENTORY -- PERMISSION REQUIRED: Written permission shall be obtained from the Board before any disposal or sale, transfer, or other removal of a major part or all the inventory, not in the ordinary course of business by a licensed retailer of veterinary dangerous drugs.
[03-07-80...08-27-90; 16.19.15.18 NMAC - Rn, 16 NMAC 19.15.18, 03-30-02]

16.19.15.~~19~~20 REPORT OF ROBBERY, FIRE AND FLOOD: When a retail veterinary drug distributor is involved in a robbery, fire, flood or any unusual event in which dangerous veterinary drugs might be missing or damaged, the owner shall immediately file with the Board, a signed statement of the circumstances of such occurrence and evidence that local authorities were notified, if applicable.
[03-07-80...08-27-90; 16.19.15.19 NMAC - Rn, 16 NMAC 19.15.19, 03-30-02]

16.19.15.~~20~~21 CONSULTANT PHARMACIST: Any retail distributor licensed by the Board to dispense veterinary prescription drugs is required to have a consultant pharmacist.

A. Consultant pharmacists to retail distributors of veterinary prescription products are required to visit the facility every other month. Consultant pharmacists to retail distributors of veterinary prescription products that do not dispense controlled substances are required to visit the licensed facility quarterly.

B. The consultant pharmacist shall maintain a log or record of all visits and activities at the retail distributor of veterinary prescription products. That record shall document at least the following:
(1) the date of the annual review of the Policy and Procedure Manual required by 16.19.4.11 NMAC;
(2) prescriptions are in a consecutively numbered file;
(3) all procurement, distribution by prescription wholesalers, and disposition records are maintained for at least 3 years;
(4) all inventory of dangerous drugs is stored in an area not accessible to unauthorized persons;
(5) all dangerous drugs are stored according to USP/NF requirements with adequate ventilation, lighting, temperature controls and refrigeration;
(6) the facility is in compliance with all State and Federal laws and regulations for the procurement, storage and dispensing of dangerous drugs; and
(7) orientation and training of all facility employees, who have access to the dangerous drugs, to the legal requirements of dangerous drugs and to the Policy and Procedure Manual of the facility.
[06-30-99; 16.19.15.20 NMAC - Rn, 16 NMAC 19.15.20, 03-30-02]

HISTORY OF 16.19.15 NMAC:
Pre-NMAC History: The material in this part was derived from that previously filed with the State Records Center and Archives:
Regulation No. 15, Dangerous Veterinary Drug Retail Distribution, 2-7-80.
Regulation No. 15, Dangerous Veterinary Drugs - Retail Distribution, 10-24-85.
Regulation No. 15, Dangerous Veterinary Drugs - Retail Distribution, 2-2-87.
Regulation No. 15, Dangerous Veterinary Drugs - Retail Distribution, 7-27-90.

History of Repealed Material: [RESERVED]

Other History: 16 NMAC 19.15, Pharmacists - Dangerous Veterinary Drugs - Retail Distribution, filed 02-02-96, reformatted and renumbered to 16.19.15 NMAC, Dangerous Veterinary Drugs, effective 03-30-2002.